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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,150	02/17/2004	David Munn	NEWL-005/02US 142996-2008	1273

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EXAMINER	
THOMAS, TIMOTHY P	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
04/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/780,150	MUNN ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1628	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *2,98-101,103,105,106,108,124-127,129 and 131-133*.
   Claim(s) withdrawn from consideration: *1,5-7,10,17,18,20-24,26,27,43,97,102,109-123 and 128*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Timothy P Thomas/
Examiner, Art Unit 1628

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642

Continuation of 3. NOTE: the amendment to claim 2 language changing "consisting essentially of" to" consisting of", the additional recitation of one or more pharmaceutically acceptable excipients are each new limitations requiring further consideration and search.

Continuation of 11. does NOT place the application in condition for allowance because: The rejections of record are maintained for the reasons of record:

Claims 2, 98-101, 103, 105-106 remain rejected under 35 U.S.C. 102(b) as being anticipated by Van Den Eynde et al. (WO 00/66764; 2000; cited in prior Office Action).

Applicant presents an argument based on language of the amended claims. Since the claim amendment has not been entered, this argument is not relevant.

Claims 2, 98-101, 103, 105-106, 108, 124-127, 129 and 131-133 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for delaying the progression of a melanoma tumor comprising administering the combination of 1-methyl-D-tryptophan and cyclophosphamide, does not reasonably provide enablement for delaying the relapse of or progression of a melanoma tumor or any other tumor by administering 1-methyl-D-tryptophan without an additional chemotherapeutic agent.

Applicant argues the embodiment of delaying the relapse of a tumor has been removed from the claims. This argument is not relevant because the claim amendment has not been entered.

Applicant further argues that because delaying the progression of two cell lines, for a melanoma and a lung tumor are enabled, the fact that the claimed method has worked in two very different cancers fully enables one skilled in the art to be able to practice the invention free of undue experimentation; that the Examiner has not shown what type of undue experimentation would be necessary for one of ordinary skill in the art to apply the claimed method to cancers other than melanoma and lung tumors, that one of ordinary skill in the art would not be unduly burdened by applying the methods of the current invention, which have proven to be useful in two very different cancers, to any cancer. Delaying the relapse of any tumor, including lung and melanoma lines, is still within the scope of the claims, since the claim amendment has not been entered. Delaying the relapse embodiments are not considered enabled. Furthermore, the record indicates that the claimed compound demonstrated a delay in the progression of a single melanoma cell line that has a large expression of IDO, supporting a delay in the progression of an IDO-expressing melanoma cell line; the declaration data also demonstrated that in a single lung cancer line, LLC, mice implanted with these tumors had a few days extended lifespan compared to control animals. The record does not make clear whether or not LLC is IDO expressing, as is the case for the melanoma cell line of the Hou article. This point is important with respect to the demonstrated IDO inhibition activity. In summary, one cell line with expression of IDO and a second cell line which may or may not express IDO have demonstrated delay of tumor progression with the claimed compound. However, in contrast to this, the claimed compound did not have activity in B16F10 cell lines, except when cyclophospahmide was also administered. Because the field of cancer treatment is unpredictable, the extension of these three sets of data to delaying the progression of every other cancer is unlikely to be effective other cancer types, especially for cancers without IDO expression.

Applicant argues that 1-methyl-D-tryptophan is not necessarily targeting inhibition of IDO within the tumor cell itself, but rather is targeting inhibition of the effects of IDO activity within cells of the hosts immune system, such as IDO+ dendritic cells; that it does not matter whether or not a tumor cell expressed IDO. It this general mechanism were the case, then B16F10 should have been responsive to treatment without cyclophosphamide. Figure 11D demonstrates that this is not the case; the growth of this cell line was not responsive to 1-methyl-D-tryptophan when the compound alone was administered, without cyclophosphamide.

Claims 2, 98-101, 103, 105-106, 108, 124-127, 129 and 131-133 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant presents an argument based on the claim amendment. Since the amendment has not been entered, the argument is not relevant.